

## DATA EVALUATION RECORD

**Sodium ferric ethylenediaminetetraacetate acid iron (III) sodium salt (FeNaEDTA)**

**STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)**

**Description of Beginning Materials (OPPTS 830.1600)**

**Description of Formulation Process (OPPTS 830.1650)**

**Discussion of Formation of Impurities (OPPTS 830.1670)**

**Preliminary Analysis (OPPTS 830.1700)**

**Certified Limits (OPPTS 830.1750)**

**Enforcement Analytical Method (OPPTS 830.1800)**

**Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)**

**MRIDs 479425-01 to 47925-06**

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<b>STUDY TYPE:</b>	Product Identity and Composition (OPPTS 830.1550) Description of Beginning Materials (OPPTS 830.1600) Description of Formulation Process (OPPTS 830.1650) Discussion of Formation of Impurities (OPPTS 830.1670) Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
<b>MRID NOS:</b>	479425-01 to 47925-06
<b>DP BARCODE NO:</b>	DP 373965
<b>DECISION NO:</b>	425379
<b>TEST MATERIAL:</b>	FeNaEDTA, TGAI and Slugkil, MP
<b>SPONSOR:</b>	W. Neudorff GmbH KG, Emmerthal, Germany
<b>TESTING FACILITY:</b>	Eco-Care Technologies Inc. 8233 Thompson Place Saanichton, BC V8M 1S1 Canada
<b>AUTHOR:</b>	Dave Almond Catherine Stewart

**STUDY COMPLETED:** November 2, 2009 (MRID 479425-01)

**GOOD LABORATORY PRACTICE:** Not GLP Compliant

**CONCLUSION:** Slugkil is a MP used in the manufacturing of end-use products to control slugs and snails in residential outdoor gardens, terrestrial and greenhouse food, and non-food crops. The active ingredient is 71.42 % w/w of (99.83% w/w) FeNaEDTA. The inerts [REDACTED]

**CLASSIFICATION:** UNACCEPTABLE. To upgrade the data as acceptable the following corrections are required: 1) the name of the active ingredient has to be consistent in the CSF and product label; 2) the methods for determination of physical/chemical characteristics has to be reported, and 3) corrosion characteristics and viscosity of the TGAI are not addressed, and they are required.

\*CONTAINS CONFIDENTIAL BUSINESS INFORMATION\*

**Test Material:** Sodium ferric ethylenediaminetetraacetate acid iron (III) sodium salt (FeNaEDTA).

**PRODUCT IDENTITY AND COMPOSITION:**

The basic formulation of FeNaEDTA TGAI is 99.83% w/w of FeNaEDTA. In addition, the TGAI contains [REDACTED]

[REDACTED] Slugkil MP (EPA Reg No. 67702-GR) is a manufacturing product (MP), containing 71.42 % w/w of active ingredient, (99.83% w/w) FeNaEDTA TGAI. It is intended for use in manufacturing end-use molluscicides to control slugs and snails in residential outdoor gardens, terrestrial and greenhouse food, and non-food crops. The inert ingredient in Slugkil (EPA Reg. 67702-GR) is [REDACTED]. The PC codes and CAS Nos. for the active ingredient, FeNaEDTA, are PC Code: 139114; CAS No. 15708-41-5. The PC Code and CAS No. for inert ingredient, [REDACTED]. The inert ingredient is used in the formulation as a carrier. There is a master label, a single copy of CSF for basic formulation, and 3 individual CSF copies for alternate formulations. **The CSFs list the chemical name of the active ingredient as "Ferric Sodium EDTA", while the labels refer to the active ingredient as "Sodium Ferric EDTA."**

**Deficiencies:** The name of the active ingredient listed on the CSF must be consistent with the chemical name of the active ingredient listed on the label. There are 2 addresses of suppliers for inert ingredient listed on the CSF that are not reported in MRID 479425-01. Furthermore, the address of the main supplier of inert ingredient reported on MRID 479425-01 is inconsistent with the corresponding address listed on the CSF. The active ingredient supplier, [REDACTED] reported on MRID 479425-01, is not listed on the CSF, and it is inconsistent with the addresses of active ingredient suppliers listed on the CSF. In addition, if the main supplier of the active ingredient is [REDACTED] that address should be listed first, not second place, on column 11 of the CSF.

*\*Inert ingredient information may be entitled to confidential treatment\**

*\*Manufacturing process information may be entitled to confidential treatment\**

MSDS Sheets for product ingredients do not include inert ingredient. No MSDS is submitted for [REDACTED] and no justification is provided for such omission.

**DESCRIPTION OF BEGINNING MATERIALS:**

The beginning materials for formulation of Slugkil MP are FeNaEDTA and [REDACTED]. MSDS Sheets for active ingredient are provided from supplier [REDACTED]. Beginning materials for formulation of FeNaEDTA (TGAI) and their corresponding amounts are listed in MRID 479425-04. They are: [REDACTED]

[REDACTED] MSDS are provided for all ingredients used in production process.

**Deficiency:** None

**DESCRIPTION OF FORMULATION PROCESS:**

[REDACTED]

**Deficiencies:** None.

**DISCUSSION OF FORMATION OF IMPURITIES:**

[REDACTED] In a 5- batch analysis of the product it was determined that this impurity is present in the product at [REDACTED]. All other materials used as beginning materials or formed during the process are removed so that the resulting product contains only Ferric Sodium EDTA and [REDACTED]

**Deficiencies:** None.

**PRELIMINARY ANALYSIS:**

The methods for quantifying content of active ingredient, FeNaEDTA, in Slugkil PM were EPA Analytical method 3050, "Acid Digestion of Sediments, Sludges, and Soils," used for digestion of samples, and EPA method 6010, "Inductively Coupled Plasma Mass Spectrometry" (ICP-MS), used for quantitative determination of iron in the product. Digested samples were diluted for analysis with an aqueous solution of 2% nitric acid (HNO<sub>3</sub>). Iron values were corrected for instrumental variability using cobalt (1000 µg/mL, SCP Science, NIST traceable) as an internal standard. Calibration range was from 100 to 2500 ng Fe/mL. Samples spikes were prepared from NIST traceable iron standard (1000 µg/mL, SCP Science, NIST traceable). Following ICP-OES analysis, measured concentrations of analyte present in samples were estimated by regression analysis, applying a weighted factor = 1/ concentration to the nominal concentration and to the ratio of analyte response to internal standard response (Fe/Co). Percent recovery for calibration standards and samples was estimated by the ratio of the concentration being measured to the nominal concentration. The nominal concentration was calculated by adding the observed unspiked concentration and the nominal concentration. Relative standard deviation is the ratio of the standard deviation to the mean. The analytical range of the calibration curve was from concentrations of 1 to 150 ppm Fe. The ratio of these concentrations to Cobalt standard described a linear function of x-intercept = 2.30; y-intercept = -1.58; correlation = 0.99, and RSQ = 0.99. The same batch of Slugkil MP was analyzed in triplicates for assessment of precision and accuracy of FeEDTA analytical method. Precision of percent recovery is demonstrated by a mean = 70.82 and RSD = 0.54 %. Results of concentration of Fe EDTA in Slugkil MP from 5 batch analysis, using enforcement analytical methods, showed an average concentration of active ingredient = 70.52 % ± 0.97. The content of active ingredient in individual samples ranged from 68.83 to 71.77 %. The analytical batch data was validated using a spiked sample at nominal Fe concentration of 30 µg/mL in every batch. Batch data was acceptable if within a range of ± 15% of expected concentration. Expected concentration was defined as the sum of nominal spike concentration (± 20 % LLOQ) plus observed unspiked sample concentration. The product was not analyzed for inert ingredient. The upper and lower certified limits are proposed based on knowledge of its purity and stability. Estimated nominal concentration of active ingredient in the product, Slugkil PM = 71.42 percent ± 2.59, with upper and lower limits = 74.01 and 68.83 percent, respectively. Estimated inert ingredient nominal concentration = [REDACTED] with upper and lower limits = [REDACTED] percent, respectively.

**Deficiencies:** None

**CERTIFIED LIMITS:**

The ratio of concentrations 1 to 150 of Fe (ppm) to cobalt standard described a linear function of x-intercept = 2.10; y-intercept = 0.61; correlation = 0.99 and RSQ = 0.99. Precision and accuracy of analytical method were demonstrated by average recovery of FeNaEDTA = 99.80% and RSD = 1.69 from triplicate batch analysis of Slugkil TGAI sample. The Average percent content of FeNaEDTA in the TGAI is 97.13 ± 0.51. The range of percent FeNaEDTA content in individual samples is from 96.35 to 97.86 %. Impurities were measured by [REDACTED]. The range of percent impurities was from [REDACTED]. The overall mean of [REDACTED]. The upper and lower certified limits of all ingredients are within the recommended range in guideline OPPTS 830.1750.

**Deficiencies:** None

## **ENFORCEMENT ANALYTICAL METHOD:**

The enforcement analytical method was described on page 7 of MRIDs 479425-02 and 479425-05. Certified limits of active ingredient were verified utilizing EPA Analytical Method 6010, “Inductively Coupled Plasma Mass Spectroscopy” (ICS-MS).

**Deficiencies:** None

## **PHYSICAL AND CHEMICAL CHARACTERISTICS:**

1. **Methods:** Methods are listed in Table 2.
2. **Results:** The physical/chemical properties are listed in Table 2.

Guideline	Property	Results	MRID
830.6302	Color	Yellow green	479425-06.
830.6303	Physical state	Powder	479425-06.
830.6304	Odor	Odorless	479425-06.
830.6313	Stability	Stable at room temperature	479425-06.
830.6314	Oxidation/reduction	N/A, the material is not reactive and does not contain an oxidizing or reducing agent.	479425-06.
830.6315	Flammability	N/A, the product does not contain combustible liquids.	
830.6316	Explosibility	N/A, the product is not potentially explosive based on structure.	
830.6317	Storage stability	Stable at 54 ° C for 2 weeks	479425-06.
830.6319	Miscibility	N/A, product is not a liquid and not to be diluted with petroleum solvents.	479425-06.
830.6320	Corrosion characteristics	<b>Not addressed</b>	
830.6321	Dielectric breakdown Voltage	N/A	
830.7000	pH	4 to 5 in 1% water solution	479425-06.
830.7050	UV/Visible light absorption	258 nm	479425-06.
830.7100	Viscosity	<b>Not addressed</b>	
830.7200	Melting range	Dehydrates from -80 to -140° C	479425-06.
830.7220	Boiling range	N/A, product is not liquid	
830.7300	Bulk density	0.935 ± 0.023	479425-06.
830.7370	Dissociation constant in water	Log K= 25.1	479425-06.
830.7520	Particle size	135 microns	479425-06.
830.7550	Partition coefficient	P < -3	479425-06.
830.7840	Water solubility	- 8.6 % at 20 ° C	479425-06.
830.7950	Water vapor	Dehydrates from -80 to -140° C	479425-06.

3. **Deficiencies.** Corrosion characteristics and viscosity were not addressed.